**Citation:**

de Oliveira MC, Sichieri R, Venturim Mozzer R. A low-energy-dense diet adding fruit reduces weight and energy intake in women. *Appetite.* 2008 Sep; 51 (2): 291-295. Epub 2008 Mar 7

**PubMed ID:** 18439712

**Study Design:**

Randomized Controlled Trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

The primary goal of this project was to determine whether adding three-daily snacks of similar caloric and fiber content, with varying energy density to the diet of overweight middle-aged women, will effect body weight, body mass index (BMI) and arm circumference measurements.

**Inclusion Criteria:**

Subjects included in the trial were non-smoking women between the ages of 30 and 50 years, who had a BMI of greater than 25kg/$m^2$, minimal alcohol consumption and a low physical activity level.

**Exclusion Criteria:**

- Diagnosis of diabetes
- Regular use of medicine or substances that might alter metabolism or body weight
- Disliked pears, apples or cookies
- Women are also excluded if they were receiving clinical or nutritional advice for weight loss.

**Description of Study Protocol:**

**Recruitment**

No details are provided regarding how the women were recruited.

**Design**

- The study was initiated with a two-week run in.All subjects were instructed by a dietitian in a standardized hypo-caloric diet containing 55% carbohydrate, 15% protein and 30% fat in order to produce a 250-calorie deficit daily

- After the run-in, subjects were provided, one of three snacks in a random manner: Three apples, three pears or three oat cookies daily. They were instructed to consume three meals and to eat the provided food items as snacks. Body weight, height, and mid-arm circumference were measured every two weeks. Subjects were provided the snacks throughout the 10-week intervention.

**Dietary Intake/Dietary Assessment Methodology**

Dietary intake was assessed every two weeks by a three-day diet record, collected in three consecutive days, including one weekend day.

**Blinding Used**

The study was single blind. Further details on the blinding are not provided within the manuscript.

**Intervention**

The intervention included the three daily snacks to be consumed daily for a 10-week period. The snacks consisted of three apples (300g), three pears (300g) or three oat cookies (60g).

**Statistical Analysis**

- Baseline characteristics of participants was performed by one-way analysis of variance
- Outcome measures were assessed by mixed model for repeated measures
- The models included in interaction variable between the three treatments and the time of follow-up.

**Data Collection Summary:**

**Timing of Measurements**

The text stated that end-point data was obtained at baseline and each two weeks over the 10-week intervention. However, the data presented appears to be from week zero, three, four, five, six and seven.

**Dependent Variables**

- Change in body weight
- Change in energy density
- Change in arm circumference.

**Independent Variables**

Three daily snack of apple (300g), pear (300g) or oat cookies (60g) matched for fiber, carbohydrate and protein content.

**Control Variables**

Dietary intake assessed by three-day diet records.

**Description of Actual Data Sample:**

- *Initial N:* 411 women were screened for participation
- *Attrition (final N):*

- 51 women started the trial at run-in
- 49 were randomized to treatment
- Sample size at following time-points were described as:
    - Weekend zero, N=48
    - Weekend three, N=42
    - Weekend four N=41
    - Weekend five N=38
    - Weekend six N=37
    - Weekend seven N=33
- *Age:* 30-50 years at study initiation
- *Ethnicity:* Not stated
- *Other relevant demographics:* Not stated
- *Anthropometrics:* Not stated
- *Location:* Rio de Janeiro, Brazil.

**Summary of Results:**

- Energy density decreased significantly among women consuming apples (-1.23kcal per gram, P=0.04) and pears (-1.29kcal per gram, P=0.05) compared to those consuming oat cookies.
- Energy intake decreased significantly among women consuming apples (-25kcal, P<0.001) and pears (-20kcal, P<0.01), while women consuming the oat cookies did not reduce energy intake.
- After 10 weeks, fruit-group consumers decreased their body weight (-0.93kg, P=0.0001 for the apple group and -0.84kg, P=0.0004 for the pear group) compared to the group with oat cookies added to the diet, after adjusting for age and type of treatment. The oat group had a non-significant increase in body weight (+0.21kg, P=0.35).

**Author Conclusion:**

- The authors conclude that their data shows that energy density effects calorie intake and consequently body weight when fruits are added to the diet
- They state that weight loss and reduced BMI were similar between the fruit supplementation groups, and that these were statistically different with the old cookie group subjects
- Consuming apple snacks reduced body weight by 0.93kg and those consuming pairs reduced body weight by 0.84kg throughout the course of the trial
- The authors state that their data provides evidence that the current recommendations for fruit consumption should be raised.

***Reviewer Comments:***

- *Interpretation of the data is somewhat confusing. In table 3 the data provided is through week 7 and in figures 1 and 2 the data included biweekly sessions through week 10. In the discussion, there is no clear definition as to why the data is presented in this manner*
- *In the statistics section of the paper, the authors state that the data is analyzed as "intention to treat." However, in table 3 the sample size is reduced at each time-point. In table 4 and figures 1 and 2, the sample size analyzed is not stated. It does not appear that they actually*

*unused the intention to treat model for analysis*

- *The study design section of the paper stated that it was a 10-week study with a two-week run-in period. Then, data is presented for weeks zero, three, four, five, six and seven. No mention is made that they shortened the trial. It is extremely hard to determine what they actually did.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

| **Relevance Questions** | | |
|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

| **Validity Questions** | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | No |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | No |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | No |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |

| | | |
|---|---|---|
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | No |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | No |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |

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|---|---|---|
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | N/A |
| 6.6. | Were extra or unplanned treatments described? | N/A |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | No |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | No |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | No |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | No |

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|---|---|---|
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | No |
| 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | N/A |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | No |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | No |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | No |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | No |